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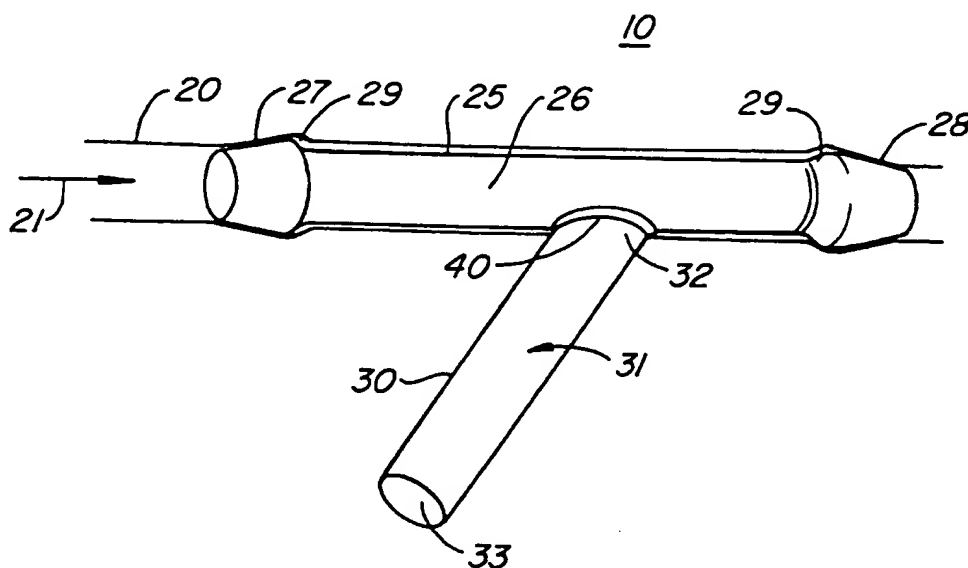
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(54) Title: SUBCUTANEOUSLY IMPLANTED CANNULA AND METHOD FOR ARTERIAL ACCESS



(57) Abstract

This invention is a catheter (10) with valve (40) for implantation in a vascular structure of a living being. The catheter is in the general shape of a "T" with the top of the "T" implanted within the lumen of a vascular structure, and the leg (30) of the "T" extending out of the vascular structure through an incision in the vascular structure. The lumen (26) of the implanted portion of the catheter completely occupies the lumen of the vascular structure, causing all blood flow through the vascular structure to be directed through the implanted portion of the catheter (10). A valve (40) is placed in the wall of the implanted portion of the catheter (10) upon application of sufficient differential pressure between the lumens of the two portions of the catheter.

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## SUBCUTANEOUSLY IMPLANTED CANNULA AND METHOD FOR ARTERIAL ACCESS

### BACKGROUND OF THE INVENTION

#### 1. The Field of Invention

10 The present invention relates to subcutaneously implanted cannulas used to access the body's circulation. More particularly, this invention provides a cannula and method for establishing intermittent vascular access using an implanted cannula in the general shape of a "T".

15 The advent of hemodialysis for the treatment of end-stage renal disease has prompted the development of many vascular access devices for the purpose of acquiring and returning large quantities of blood for passage through an extracorporeal circuit during hemodialysis procedure. Available devices have generally relied on the use of either  
20 indwelling venous catheters or flow through shunt devices which create an artificial fistula between an artery and vein.

Venous catheters are limited by relatively poor draw flows and by their tendency to be irritative resulting in vessel stenosis, thrombosis, and occasionally vessel  
25 perforation. They frequently fail because of infection, weakness in the vessel wall, poor catheter position, and/or thrombus formation in the catheter lumen. Shunt devices which create a fistulous blood flow between an artery and a vein have been the mainstay of modern vascular access for dialysis  
30 but are similarly problematic. Installation of these "shunts" is an extensive surgical procedure resulting in significant tissue trauma and pain. Once in place, the shunts result in additional cardiac output needs with as much as one-fifth of the cardiac output (approximately 1000 ml per minute) required  
35 for adequate function. In addition, the transfer of the arterial pressure wave results in damage to the vein at the point of anastomosis with the shunt and can result in intimal hyperplasia and subsequent thrombosis and shunt occlusion.

When such occlusion occurs, another vein segment must be used for shunt revision, and exhaustion of available sites is distressingly common and can be fatal. Repeated punctures of the wall of the shunt often result in eventual failure and require additional surgery to repair or replace the shunt. The expense in terms of both health care dollars and human misery is enormous.

Each of the available access technologies mentioned thus far are also complicated by the possibility of recirculation of blood already passed through the extra-corporeal circuit resulting in the loss of treatment efficiency. The harm done to patients by the "recirculation syndrome" is insidious and at times undetected until great harm has been done.

Indwelling catheters which occupy only a portion of the vessel lumen are subject to movement within the vessel, which can cause irritation or even vessel perforation. Further, catheters which occupy only a portion of the vessel lumen, and which are inserted or threaded through the lumen for substantial distances tend to disrupt the normal flow of blood through the vascular structure, altering the hemodynamics of the blood flow in a manner which can damage the vessel, the components of the blood, and which can encourage thrombosis. Such catheters are generally unsuitable for long term implantation in arteries.

What is needed is a cannula that can be implanted within an artery and that will cause minimal disruption of blood flow through the lumen of the artery during use and nonuse of the cannula, which does not cause vessel stenosis, thrombosis, or vessel perforation, which is capable of handling large quantities of blood, and which will retain its usefulness for a long period of time after implantation.

## 2. Description of the Background Art

Vascular access employing indwelling catheters is described in a number of patents and publications including U.S. Patent Nos. 3,888,249; 4,543,088; 4,634,422; 4,673,394; 4,685,905; 4,692,146; 4,695,273; 4,704,103; 4,705,501;

4,772,270; 4,846,806; 5,053,613; 5,057,084; 5,100,392;  
5,167,638; 5,108,365; 5,226,879; 5,263,930; 5,281,199;  
5,306,255; 5,318,545; 5,324,518; 5,336,194; 5,350,360;  
5,360,407; 5,399,168; 5,417,656; 5,476,451; 5,503,630;  
5 5,520,643; 5,527,277; and 5,527,278; and EP 228 532; and  
Wigness et al. (1982) paper entitled "Biodirectional  
Implantable Vascular Access Modality" presented at the Meeting  
of the American Society for Artificial Internal Organs, April  
14-16, 1982, Chicago, Illinois.

10 Catheters having distal valves are described in a  
number of patents including U.S. Patent Nos. 274,447;  
3,331,371; 3,888,249; 4,549,879; 4,657,536; 4,671,796;  
4,701,166; 4,705,501; 4,759,752; 4,846,806; 4,973,319;  
5,030,710; 5,112,301; 5,156,600; and 5,224,978.

15 Implantable dialysis connection parts are described  
in a number of patents including U.S. Patent Nos. 4,692,146;  
4,892,518; 5,041,098; 5,180,365; and 5,350,360.

#### SUMMARY OF THE INVENTION

20 The present invention provides improved implantable  
vascular cannulas which are particularly useful for providing  
long-term access to the arterial vasculature, including both  
native arteries and artificial arterial lumens (such as an  
arteriovenous (AV) shunt or an arterial graft. The cannulas  
25 of the present invention comprise a tubular body which is  
implantable within an arterial lumen and an access leg having  
one end attached to a side wall of the tubular body. Both the  
tubular body and the access leg have lumens therethrough, with  
the lumen of the tubular body being configured to receive the  
30 entire blood flow of the arterial lumen in which it is  
implanted. The access leg, which is attached to the tubular  
body in a generally T-shaped configuration, thus provides for  
access into the lumen of the tubular body for either  
withdrawing blood (e.g. for hemodialysis or other extra-  
35 corporeal treatment) or for introducing drugs or other media  
into the arterial blood flow.

The arterial access cannula may be implanted either  
subcutaneously or transcutaneously. By transcutaneous, it is

5 meant that a portion of the access leg will pass outwardly through the patient's skin to permit direct arterial access using external drug pumps, syringes, or other equipment. It will be appreciated, of course, that a hemostasis valve must be provided on the access leg to prevent uncontrolled blood loss. Usually, any transcutaneous use of the cannula of the present invention will be only for a short time.

10 More usually, the cannula of the present invention will be intended for subcutaneous use. In that case, an access port is connected to the open end of the access leg and is also subcutaneously implanted beneath the patient's skin. The access port will be suitable for attachment to needles, tubes, catheters, and other devices which may be percutaneously introduced into the access port to provide a  
15 desired external connection. An example of an access port comprises a chamber having a penetrable membrane on one side thereof. Temporary access to the chamber is formed by penetrating the needle, tube, or catheter through the penetrable membrane.

20 In all cases, the T-configured arterial cannula of the present invention is an improvement over prior indwelling catheters in a number of respects. The tubular body is firmly anchored within the artery and not subject to being moved or dislodged by blood flow. Thus, trauma to the arterial wall from movement of the cannula is significantly lessened.  
25 Moreover, by assuring that the lumen of the tubular body has a cross-sectional shape and dimensions which closely match those of the arterial lumen, smooth blood flow through the cannula can be enhanced while the risk of thrombus formation is substantially reduced.  
30

In a preferred construction, the arterial cannula will include an isolation valve, at or near the junction between the access leg and the tubular body. The isolation valve can be any type of valve that closes or inhibits flow  
35 between the tubular body lumen and the access leg lumen in the absence of a pressure drop therebetween. Thus, when blood is not being withdrawn and/or when drugs or other media are not being introduced, the isolation valve will close and isolate

the lumen of the access leg from arterial blood flow. Such isolation is a significant advantage since it reduces the risk of thrombus formation within the access leg and thrombus release into the arterial lumen. Often, it will be desirable to flush the lumen of the access leg with an anti-coagulant fluid after each use. The removal of static blood and the placement of the anti-coagulant fluid further decreases the risk of thrombus formation and release. The isolation valve may be in a variety of forms, including slit valves, flap valves, ball valves, and may further be configured to provide for one-way or bi-direction flow. For example, in the case of arterial cannulas used for withdrawing blood, it will often be advantageous to have a one-way isolation valve which permits blood flow from the tubular body into the access leg, but inhibits reverse flow of any materials from the access leg into the lumen. In the case of drug and other infusions into the artery, it may be desirable to provide a one-way isolation valve which permits such introduction, but prevents reflux of blood into the access leg. A particularly preferred valve is a slit valve formed into the wall of the tubular body, as illustrated in detail hereinafter. When such a slit valve is closed, the inner profile of the tubular body lumen will be substantially smooth and free from discontinuities caused by the valve.

The arterial cannula may be formed from any one or a combination of a variety of biocompatible materials. By biocompatible, it is meant that the material(s) will be suitable for a long term implantation within patient vasculature and tissue and will be free from immunogenicity and inflammatory response. Usually, the cannula will be formed in whole or in part from an organic polymer, such as silicone rubber, polyethylenes, polyurethanes, polyvinylchloride, polytetrafluoroethylene (PTFE), polysulfone, or the like. Portions of the cannula may be reinforced, for example the access leg may include circumferential reinforcement to enhance its hoop strength without significantly diminishing flexibility. Such reinforcement may take the form of a helical wire or ribbon,

axially spaced- apart hoops, or the like. Preferably, the reinforcement may be achieved by molding the access leg to incorporate circumferential corrugation, i.e. a plurality of axially spaced-apart circumferential ribs along all or a portion of its lengths. In all cases, it is desirable that the internal lumen of the access leg and the tubular body remain as smooth as possible to avoid disturbances to blood flow.

The tubular body of the arterial cannula will have dimensions compatible with implantation within a variety of arteries, including both native (natural) arteries and implanted synthetic arteries. The most common native arteries in which the cannulas may be implanted include the proximal ulnar, proximal radial, brachial artery, axillary artery, and subclavian artery. Implanted synthetic arteries include bypasses, shunts (e.g. AV shunts), arterial grafts, and the like. Both native arteries and implanted synthetic arteries have lumens, and reference to "arterial lumens" herein is intended to refer to both such lumens.

Generally, the length of the tubular body will be in the range from 10 mm to 50 mm and the outer diameter will be in the range from 3 mm to 10 mm. The diameter of the lumen of the tubular body will generally be in the range from 1 mm to 8 mm. The access leg will usually have a length in the range from 25 mm to 700 mm and an outer diameter in the range from 3 mm to 10 mm. The lumen diameter of the access leg will generally be in the range from 2 mm to 8 mm.

In a preferred aspect of the present invention, at least a portion of the access leg of the arterial cannula will be sufficiently compliant so that substantially no forces are transmitted from the access leg back into the tubular body. For proper functioning of the arterial cannula, it is important that the tubular body remain properly aligned within the arterial lumen. This can be achieved by fabricating at least a portion of the access leg adjacent to the tubular body to have a low bending stiffness. The hoop strength of the access tube, in contrast, should remain relatively high, being at least sufficient to maintain patency of its lumen at



internal pressures below -250 mmHg, preferably below -400 mmHg. Use of the helical reinforcement designs described above helps assure that the access leg can be sufficiently flexible while retaining sufficient strength.

5           In a first specific aspect of the present invention, a system for performing extracorporeal blood treatment comprises an arterial cannula as described above in combination with a venous cannula which is implantable within a venous lumen. The venous cannula will also comprise an  
10 access leg, but will usually be in the form of a conventional in-dwelling catheter or a distal portion of the cannula as within the venous lumen in a generally free or unrestricted manner. The use of conventional in-dwelling cannula in the venous vasculature is not problematic. Usually, both the  
15 arterial cannula and the venous cannula of the systems of the present invention will further include access ports intended to be connected to catheters for completing an extracorporeal circuit. Such access ports may be of generally conventional construction and may be connected to extracorporeal treatment  
20 circuits in a general conventional manner.

          In another aspect, the present invention comprises a method for implanting an arterial access cannula within the lumen of an artery. The method comprises surgically exposing the artery and making an incision in its wall. The tubular  
25 body of the access channel is introduced through the incision and into the lumen of the artery. The lumen of the tubular body will be evenly circumferentially aligned with the arterial lumen, and the incision then closed. In some instances, the tubular body will have flared portions at  
30 either end, and the flared portions can optionally be tied within the artery to further anchor the cannula therein. The method may further comprise an initial step of determining a cross-sectional dimension of the artery and selecting a tubular body having a cross-section dimension substantially  
35 equal to that of the arterial lumen. The method may still further comprise subcutaneously introducing an arterial port, where the arterial port is connected or connectable to the access leg of the arterial access cannula. The arterial port

may be introduced through the same incision as the arterial cannula. Alternatively, the arterial port may be introduced through a second incision formed remotely from the first incision, and the port thereafter connected to the access leg  
5 by forming a subcutaneous path between the two.

The method may still further comprise introducing a venous cannula by surgically exposing a vein, and introducing the venous cannula therethrough. The venous port may then be introduced, either through the same or a different surgical  
10 incision, in order to form a desired subcutaneous access assembly. By having introduced both an arterial cannula and a venous cannula, the patient is ready for access to hemodialysis or a variety of other extracorporeal treatment modalities.

In still further aspects of the present invention, methods are provided for performing extracorporeal blood treatment by percutaneously attaching a first catheter to an access leg of a subcutaneously implanted arterial cannula having a tubular body disposed within an arterial lumen. A  
20 second catheter is then percutaneously attached to a subcutaneously implanted venous access catheter, and blood may be circulated from the first catheter through an extracorporeal circuit to the second catheter. The first and/or second catheters are typically percutaneously  
25 penetrated to connect to the access leg, e.g. by penetrating a needle or needle-introduced catheter through a membrane of a conventional access port. The extracorporeal circuit may be used for hemodialysis, and the method may further comprise stopping blood circulation and filling at least the access leg of the  
30 arterial cannula with an anti-coagulant fluid.

In still a further aspect of the present invention, a method for administering a fluid medium into an artery comprises percutaneously attaching a needle or needle-introduced catheter to an access leg of a subcutaneously  
35 implanted arterial cannula having a tubular body implanted within the arterial lumen. The fluid medium is then infused through the needle or catheter into the access leg and from there into the lumen of the tubular body. The fluid medium

will usually be a medication, but could also be a diagnostic or other conventional agent introduced to arterial blood flow.

#### BRIEF DESCRIPTION OF THE DRAWINGS

5           Fig. 1 shows a perspective view of the preferred embodiment of the present invention implanted within a vascular structure.

          Fig. 2 shows a cross-sectional view of the preferred embodiment of the present invention.

10           Fig. 3 shows a cross-sectional view of the valve of the preferred embodiment of the present invention in the closed position.

          Fig. 4 shows a cross-sectional view of the valve of the preferred embodiment of the present invention in the open position.

15           Figs. 5 and 6 are top and side elevational views, respectively, of a percutaneous access port which may be utilized with either the arterial cannula or venous cannula of the present invention.

20           Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 5.

          Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 5.

25           Fig. 9 is an isometric view of a second embodiment of an arterial cannula constructed in accordance with the principles of the present invention.

          Fig. 10 is a detailed view of the tubular body of the cannula of Fig. 9 shown in partial cross-section.

30           Fig. 11 illustrates subcutaneous implantation of the arterial cannula of Fig. 9 in tissue.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

35           Referring to Fig. 1 there is depicted an arterial cannula 10 constructed in accordance with the principles of the present invention implanted within an arterial lumen 20. The cannula is shaped generally like a "T" and is comprised of two primary sections; the tubular body 25 and the access leg 30. The intravascular tube 25 is an elongated tube having a

single lumen 26, open on both ends. When implanted within the lumen 20, the tubular body 25 will have an upstream end 27, and a downstream end 28, determined by the direction of blood flow in the vascular structure 20. In Fig. 1 the direction of blood flow is indicated by the arrow 21. The cannula  
5 however, can be implanted in either orientation.

The access leg 30 is an elongated tube having a single lumen 31. A distal end 32 of the access leg 30 is connected to the tubular body 25, generally near the mid-point  
10 thereof. The access leg 30 may extend from the tubular body 25 at any angle, including a 90 degree angle, but it is preferred that the access leg 30 of the cannula 10 extend from the tubular body 25 in a direction which is inclined toward the upstream end 27 of the tubular body 25. The angle formed  
15 between the access leg 30 and the upstream end 27 of the tubular body 25 is an acute angle. The angle formed between the access leg 30 and the downstream end 28 of the intravascular tube 25 is an obtuse angle. A preferred angle between the access leg 30 and the upstream end 27 of the  
20 tubular body 25 is between 30° and 60°, usually being approximately 45 degrees.

A valve 40 is preferably located at the point of connection between the distal end 32 of the access leg 30 and the tubular body 25. The preferred valve 40 is a slit valve.  
25 Such valves are well known in the art. As best shown in Fig. 3, the slit valve is comprised of a membrane 41 which has a slit 42 extending partially across the membrane 41 and completely through the membrane 41. The membrane 41 acts to prevent fluid flow through the lumen 31 of the access leg 30,  
30 except when adequate differential pressure exists on opposite sides of the membrane 41 to cause the slit 42 to open, as is shown in Fig. 4. The membrane 41 is located such that the side of the membrane 41 located towards the vascular structure is essentially flush with the inner wall of the intravascular  
35 tube 25. When the catheter 10 is not in use, the membrane 41 of the valve 40 and the inner surface of the tubular body 25 form a continuous tube that has minimal impact on normal blood flow through the arterial lumen.

In the preferred embodiment, the membrane 41 is comprised of a portion of the side wall of the tubular body 25. To create the valve 40, a slit 42 is cut in the side wall of the tubular body 25 to correspond to the point of  
5 connection of the access leg 30. In this manner, when the valve is closed, the inner surface of the tubular body 25 is a continuous smooth surface which has minimal impact on normal blood flow. When the valve 40 opens, fluid flow between the lumen 31 and the access leg 30 and the lumen 26 of the  
10 intravascular tube 25 occurs.

The outer circumference of the tubular body 25 is provided with expanded barbs 29 to hold cannula 10 in place within the vascular structure 20. One each of these expanded barbs 29 may be placed proximate the upstream end 27 and  
15 proximate the downstream end 28 of the tubular body 25. The expanded barbs 29 have an enlarged outer circumference which tends to slightly distend the wall of the arterial lumen 20, providing a snug fit, but not preventing the continued viability of the arterial wall. Additional areas of expanded  
20 outer diameter (not shown) may be spaced along the outer surface of the tubular body 25. The fit between the arterial wall and the tubular body 25 must be of sufficient tightness to prevent passage of blood between the arterial wall and the outer surface of the tubular body 25. Optionally, it may be  
25 possible to place ties or clamps (not shown) about the outer wall of the artery adjacent to the expanded barbs 29 to hold the cannula 10 in place. All blood flowing through the arterial lumen should pass through the lumen 26 of the tubular member 25.

30 In use, the proximal end 33 of the access leg 30 of the cannula 10 may be connected to a subcutaneous port, or may extend transcutaneously (i.e. through the skin). The cannula 10 is suitable for use with any device requiring or  
35 facilitating intermittent vascular access. The cannula 10 of the present invention is particularly useful for arterial access in hemodialysis, since such treatment requires large quantity blood flow, and requires relatively frequent vascular access over a long period of time. For such use two cannulas

10 may be surgically implanted. One of the devices is implanted in an artery. The other device is implanted in a vein. Usually, however, a conventional in-dwelling catheter will be used for the venous access since vein access is easier to establish. In this manner both the venous and arterial circulations are accessed separately, without fistulous communication. Current use of shunts, which create a fistulous connection between artery and vein, not only involve a more extensive surgical procedure, but are fraught with problems including increased cardiac output requirements, damage to the vein due to arterial pressure waves, and frequent shunt occlusion or thrombosis.

During hemodialysis, blood is removed from the arterial cannula 10 implanted in an artery and is subjected to the extracorporeal dialysis circuit. Removal occurs by reducing the pressure in the access leg 30 of the cannula 10, until the slit valve 40 opens, and blood flows from the tubular body 25 into the access leg 30. The treated blood is returned to a cannula implanted in a vein. At the completion of the dialysis treatment of the access leg 30 of cannula 10 is filled with anti-coagulant fluid, to discourage thrombosis and occlusion of the access legs 30. A similar process may be used for apheresis or exchange transfusion procedures. Additionally, a single arterial cannula 10 may be used for frequent administration of medication into artery or vein, or for large volume fluid infusions.

Surgical implantation of the arterial cannula 10 is a straight forward procedure. The chosen artery is located and isolated, and a small incision is made in the luminal wall. The tubular body 25 of the cannula 10 is inserted into the incision, with the access leg 30 extending out of the lumen through the incision. The incision is then sutured to provide a snug fit around the access leg 30. The proximal end 33 of access leg 30 of the cannula 10 is then attached to a subcutaneous port (described hereinafter) or other device requiring intermittent vascular access.

Materials of construction well known in the art may be used for the manufacture of the cannula 10. However, it is

important that the tubular body 25 be particularly biocompatible with the arterial wall 20, since it is intended that the wall in contact with the cannula 10 remain viable. Since the cannula 10, unlike most prior art catheters, is not  
5 designed to be pushed or threaded some distance into a blood vessel, the access tube of the cannula may be comprised of relatively flexible material. This may be accomplished by including a spring or other reinforcement element (not shown) within the walls of the cannula 10 to maintain hoop strength.  
10 The materials of construction of the tubular body should be of sufficient rigidity to maintain the preferred angle between the access leg 30 and the tubular body. The dimensions of the catheter 10 depend upon the size of the vascular structure 20 to be accessed. Typically the outer diameter of the tubular  
15 body 25 will be between 3 and 10 mm, with a wall thickness of approximately 0.5 to 1 mm, yielding a lumen 26 diameter of between 1 and 8 mm. A typical length of the tubular body 25 from upstream end 27 to downstream end 28 is between 10 and 50 mm. The maximum diameter of the outer surface of the  
20 expanded barbs 29 is approximately 30 percent greater than the diameter of the tubular body 25 where no expanded barb 29 is present. The length and flexibility of the access leg can vary depending upon the use of the catheter 10. For use with subcutaneous ports an access leg 30 length of approximately 25  
25 mm to 700 mm, usually about 100 mm is generally sufficient.

Referring now to Figs. 5-8, an exemplary implantable port 100 will be described. The implantable port 100 may be used with either the arterial cannula 10 described above, or with more conventional in-dwelling cannula which may be used  
30 in systems for venous access, as described in more detail hereinafter. The port 100 includes a single hematologic chamber 125, where the base and sides are formed by a circumferential wall 126. The port 100 further includes wall 126 and a cover 120 which holds a replaceable diaphragm 127 in  
35 place. The cover 120 is removable to allow replacement of the diaphragm 127 if needed. A base 129 of the port 100 comprises a flange having apertures 130 which permit fastening of the port to underlying tissue, typically using sutures. A

connector 128 open to one end of the chamber 125 is connectable to the free end of access leg 30 which forms part of the arterial cannula 10 described above.

Referring now to Figs. 9 and 10, an alternative embodiment of an arterial cannula 200 constructed in accordance with the principles of the present invention will be described. The cannula 200 includes both a tubular body 202 and an access leg 204. The access leg 204 comprises a portion adjacent to the tubular body 202 including a plurality of circumferential ribs or corrugations 206 which provides substantial hoop strength to the leg without diminishing the desired flexibility. The remainder of the access leg 204 comprises larger sections 208, with the distal end 210 being suitable for attachment to the vascular port 100 at connector 128, as described previously.

The tubular body 202 comprises a molded insert 230 including a main body portion 32 and a branch portion 234. An isolation valve 36 is formed at the end of branch 234, generally as described above with previous embodiments. Tubular body 202 is connected to the adjacent end of the access leg 206 by over molding an exterior body 238. Usually, a titanium tube 240 is placed within the junction between the end of access leg 206 and the end of branch portion 234. The tube may be titanium or other biocompatible metal. The insert 230 is typically formed from a relatively soft material, such as 40D to 50D silicone rubber. The outer portion 238 of the tubular body 202 is formed from a similar material, such as 50 D silicone rubber. The access tube may be also formed from silicone having a hardness of 40D to 50D. Conventional molding techniques may be used to form all these parts.

Referring now to Fig. 11, the tubular body 202 of the arterial cannula 200 may be implanted within an artery A by first surgically exposing the artery and thereafter forming an incision in the side of the artery. The tubular body 202 is the introduced through the incision, and the incision sutured to hold the body within the arterial lumen. The access leg 204 is then moved to a location where the arterial port 100 is to be implanted. Note that the entire assembly of



the arterial cannula 200 and arterial port 100 may be implanted together within a single incision. Alternatively, the arterial cannula 200 and the arterial port 100 may be separately implanted, with the access leg 204 being separately positioned therebetween.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

- 1           1. A system for performing extracorporeal blood  
2 treatment, said system comprising:  
3           an arterial cannula including a tubular body adapted  
4 to be implanted within an arterial lumen and a tubular access  
5 leg having a first end connected to a junction on the tubular  
6 body, wherein blood flowing through a lumen of the tubular  
7 body can selectively flow out through the access leg; and  
8           a venous cannula implantable within a venous lumen  
9 and including an access leg to selectively permit blood return  
10 to the venous lumen.
- 1           2. A system as in claim 1, further comprising an  
2 arterial port adapted to be connected to a second end of the  
3 access leg of the arterial cannula and to receive percutaneous  
4 attachment of an arterial catheter.
- 1           3. A system as in claim 2, further comprising a  
2 venous port adapted to be connected to an end of the access  
3 leg of the venous cannula.
- 1           4. A system as in claim 3, wherein the venous  
2 cannula consists essentially of the access leg and is adapted  
3 to be planted freely within the venous lumen.
- 1           5. A system as in claim 1, wherein the tubular  
2 body has a length in the range from 10 mm to 50 mm and an  
3 outer diameter in the range from 3 mm to 10 mm.
- 1           6. A system as in claim 5, wherein the access leg  
2 has a length in the range from 25 mm to 700 mm and an outer  
3 diameter in the range from 3 mm to 10 mm.
- 1           7. A system as in claim 1, wherein at least a  
2 portion of the access leg is sufficiently compliant so that no  
3 substantial forces may be transmitted to the tubular body  
4 through the access leg.

1           8. A system as in claim 7, wherein at least a  
2 portion of the access leg adjacent to the tubular body has a  
3 bending stiffness which is less than that of the adjacent  
4 tubular body.

1           9. A system as in claim 8, wherein said portion of  
2 the access leg has a hoop strength sufficient to withstand an  
3 internal pressure of -250 mmHg.

1           10. A system as in claim 1, wherein the tubular  
2 body is circumferentially reinforced.

1           11. A system as in claim 10, wherein the  
2 circumferential reinforcement comprises a helical wire or  
3 circumferential corrugation.

1           12. A system as in claim 1, wherein the access leg  
2 is circumferentially reinforced.

1           13. A system as in claim 12, wherein the  
2 circumferential reinforcement comprises a helical wire or  
3 circumferential corrugation.

1           14. A system as in claim 1, further comprising a  
2 pressure-responsive valve at the junction, said valve  
3 inhibiting blood flow across the junction in the absence of a  
4 pressure differential thereacross.

1           15. A system as in claim 14, wherein the valve is  
2 incorporated in the tubular body so that no structure of the  
3 valve intrudes into the vascular lumen.

1           16. A system as in claim 15, wherein the valve is a  
2 slit valve formed in the tubular body at the junction.

1           17. An arterial cannula comprising:  
2           a tubular body having a first end, a second end; and  
3           a lumen therebetween, wherein the tubular body is  
4 adapted to be implanted within an arterial lumen; and  
5           a tubular access leg having a first end connected to  
6 the tubular body at a junction, a second end, and a lumen  
7 therebetween, wherein the access tube lumen is fluidly coupled  
8 to the tubular body lumen at the junction.

1           18. An arterial cannula as in claim 17, wherein the  
2 tubular body has a length in the range from 10 mm to 50 mm and  
3 an outer diameter in the range from 3 mm to 10 mm.

1           19. An arterial cannula as in claim 18, wherein the  
2 access leg has a length in the range from 25 mm to 700 mm and  
3 an outer diameter in the range from 3 mm to 10 mm.

1           20. An arterial cannula as in claim 17, wherein at  
2 least a portion of the access leg is sufficiently compliant so  
3 that no substantial forces may be transmitted to the tubular  
4 body through the access leg.

1           21. An arterial cannula as in claim 20, wherein at  
2 least a portion of the access leg adjacent to the tubular body  
3 has a bending stiffness which is less than that of the  
4 adjacent tubular body.

1           22. An arterial cannula as in claim 21, wherein  
2 said portion of the access leg has a hoop strength sufficient  
3 to withstand an internal pressure of -250 mmHg.

1           23. An arterial cannula as in claim 17, wherein the  
2 tubular body is circumferentially reinforced.

1           24. An arterial cannula as in claim 23, wherein the  
2 circumferential reinforcement comprises a helical wire or  
3 circumferential corrugation.

1           25. An arterial cannula as in claim 23, wherein the  
2 access leg is circumferentially reinforced.

1           26. An arterial cannula as in claim 25, wherein the  
2 circumferential reinforcement comprises a helical wire or  
3 circumferential corrugation.

1           27. An arterial cannula as in claim 17, further  
2 comprising a pressure-responsive valve at the junction, said  
3 valve inhibiting blood flow across the junction in the absence  
4 of a pressure differential thereacross.

1           28. An arterial cannula as in claim 27, wherein the  
2 valve is incorporated in the tubular body so that no structure  
3 of the valve intrudes into the vascular lumen.

1           29. An arterial catheter as in claim 28, wherein  
2 the valve is a slit valve formed in the tubular body at the  
3 junction.

1           30. A method for implanting an arterial access  
2 cannula within a lumen of an artery, said method comprising:  
3 surgically exposing the artery;  
4 making an incision in a wall of the artery;  
5 introducing a tubular body of the access cannula  
6 through the incision and into the lumen of the artery so that  
7 a lumen of the tubular body is evenly aligned with the  
8 arterial lumen and an access leg of the cannula is aligned  
9 through the incision; and  
10 closing the incision and securing the tubular body  
11 within the arterial lumen.

1           31. A method as in claim 30, wherein the artery is  
2 selected from the group consisting of the proximal ulnar,  
3 proximal radial, brachial artery, axillary artery, subclavian  
4 artery and synthetic arteries.

1           32. A method as in claim 30, wherein the lumen of  
2 the tubular body is selected to have a cross-sectional  
3 dimension substantially equal to that of the blood vessel.

1           33. A method as in claim 32, further comprising the  
2 steps of determining a cross-sectional dimension of the artery  
3 and selecting a tubular body having a cross-sectional  
4 dimension substantially equal to that of the arterial lumen.

1           34. A method as in claim 30, wherein the tubular  
2 body has an outer diameter in the range from 10 mm to 50 mm  
3 and a length in the range from 3 mm to 10 mm.

1           35. A method as in claim 30, further comprising  
2 subcutaneously introducing an arterial port wherein the  
3 arterial port is connected or connectable to the access leg of  
4 the arterial access cannula.

1           36. A method as in claim 35, wherein the arterial  
2 port is introduced through the incision.

1           37. A method as in claim 35, wherein the arterial  
2 port is introduced through a separate incision remote from the  
3 first incision, and thereafter connected to the access leg of  
4 the arterial access cannula.

1           38. A method as in claim 30, further comprising  
2 surgically exposing a vein;  
3           introducing a venous cannula through the wall of the  
4 vein; and  
5           introducing a venous port subcutaneously, wherein  
6 the venous port is connected or connectable to the venous  
7 catheter.

1           39. A method as in claim 38, wherein the venous  
2 cannula and the venous port are introduced through a single  
3 incision.

1           40. A method as in claim 38, wherein the venous  
2 cannula and the venous port are introduced through separate  
3 incisions and thereafter connected.

1           41. A method for performing extracorporeal blood  
2 treatment, said method comprising:  
3           percutaneously attaching a first catheter to an  
4 access leg of a subcutaneously implanted arterial cannula  
5 having a tubular body disposed within an arterial lumen;  
6           percutaneously attaching a second catheter to a  
7 subcutaneously implanted venous access cannula; and  
8           circulating blood from the first catheter through an  
9 extracorporeal circuit to the second catheter.

1           42. A method as in claim 41, wherein the arterial  
2 lumen is present in an artery selected from the group  
3 consisting of the proximal ulnar, proximal radial, brachial  
4 artery, axillary artery, subclavian artery and synthetic  
5 arteries.

1           43. A method as in claim 41, wherein the lumen of  
2 the tubular body is selected to have a cross-sectional  
3 dimension substantially equal to that of the arterial lumen.

1           44. A method as in claim 41, wherein the tubular  
2 body has an outer diameter in the range from 10 mm to 50 mm  
3 and a length in the range from 3 mm to 10 mm.

1           45. A method as in claim 41, wherein at least the  
2 first catheter is accessed by penetrating a needle or a  
3 needle-introduced catheter to attach to the access leg.

1           46. A method as in claim 45, wherein the access leg  
2 includes a port comprising a penetrable membrane and the  
3 needle or needle-introduced catheter is penetrated through the  
4 membrane.

1           47. A method as in claim 41, wherein the  
2 extracorporeal circuit is a hemodialysis circuit or an  
3 apheresis circuit.

1           48. A method as in claim 41, further comprising  
2 stopping circulation and filing at least the arterial cannula  
3 with an anticoagulant fluid.

1           49. A method as in claim 48, wherein the anti-  
2 coagulant fluid is maintained within the cannula by a valve  
3 disposed near the distal end of the access leg.

1           50. A method for administering fluid medium into an  
2 artery, said method comprising:  
3           percutaneously attaching a needle or needle-  
4 introduced catheter to an access leg of a subcutaneously  
5 implanted arterial cannula having a tubular body implanted  
6 within an arterial lumen;  
7           infusing a fluid medium through the needle or  
8 needle-introduced catheter into the access leg and to the  
9 blood passing through the lumen of the tubular body.

1           51. A method as in claim 50, wherein the artery is  
2 selected from the group consisting of the proximal ulnar,  
3 proximal radial, brachial artery, axillary artery, subclavian  
4 artery and synthetic arteries.

1           52. A method as in claim 50, wherein the lumen of  
2 the tubular body is selected to have a cross-sectional  
3 dimension substantially equal to that of the blood vessel.

1           53. A method as in claim 50, wherein the tubular  
2 body has an outer diameter in the range from 10 mm to 50 mm  
3 and a length in the range from 3 mm to 10 mm.

1           54. A method as in claim 50, wherein a valve is  
2 disposed at the end of the access leg adjacent to the tubular.



1           55. A method as in claim 54, wherein the valve is a  
2 slit valve extending across the cannula near its distal end.

1           56. A method as in claim 55, further comprising  
2 filling the access leg of the cannula with an anti-coagulant  
3 fluid when medication is not being introduced therethrough.

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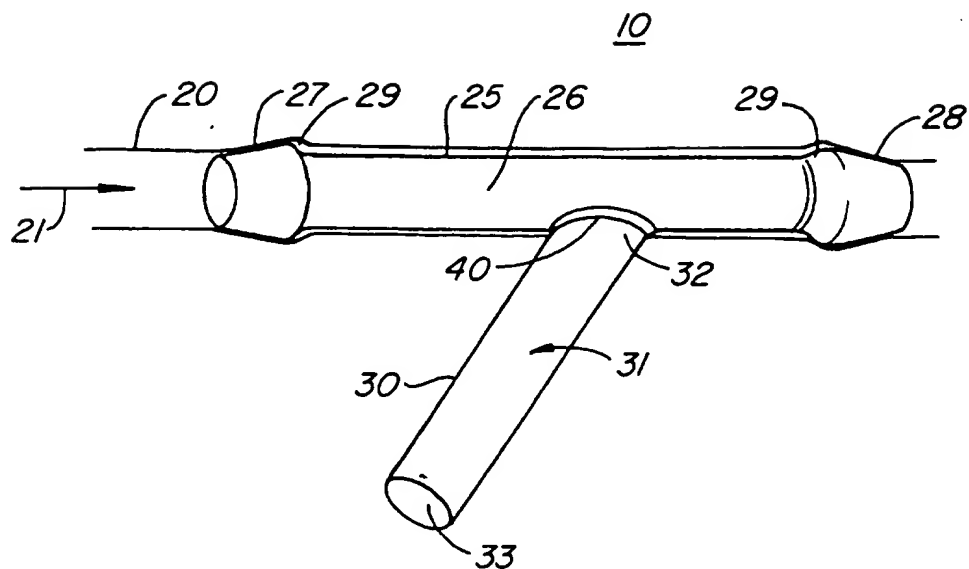


FIG. 1.

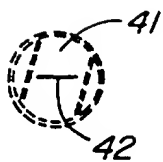


FIG. 3.

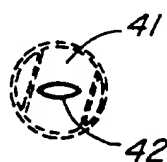


FIG. 4.

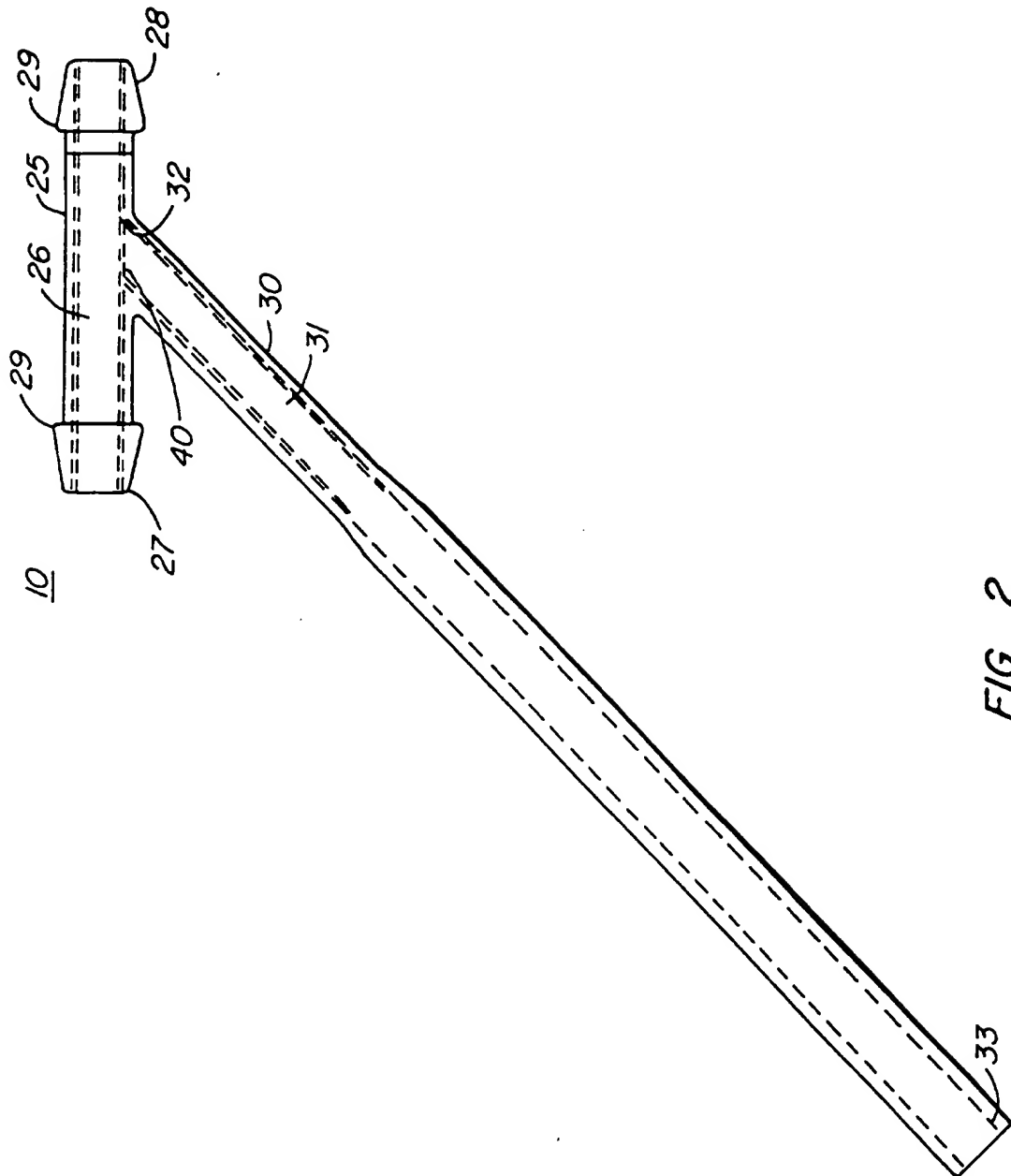


FIG. 2.

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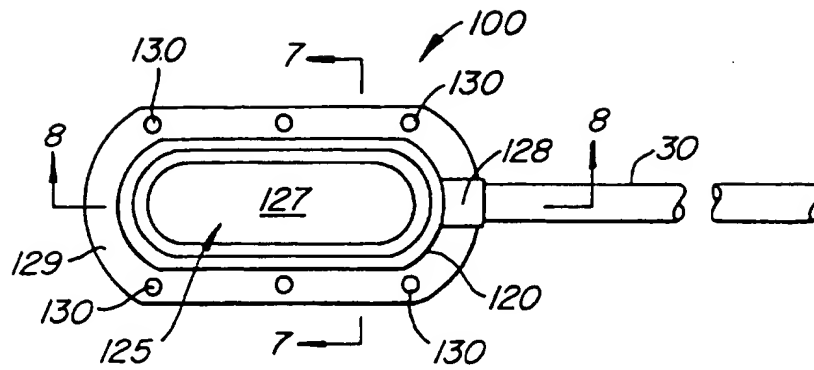


FIG. 5.

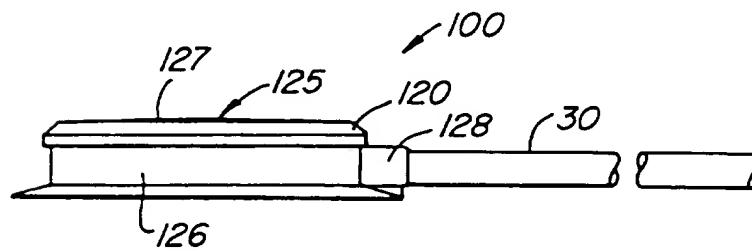


FIG. 6.

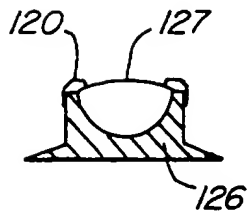


FIG. 7.

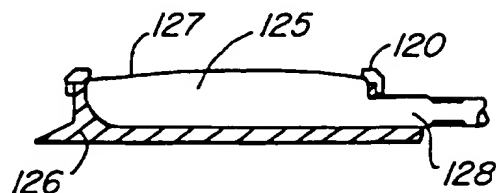


FIG. 8.

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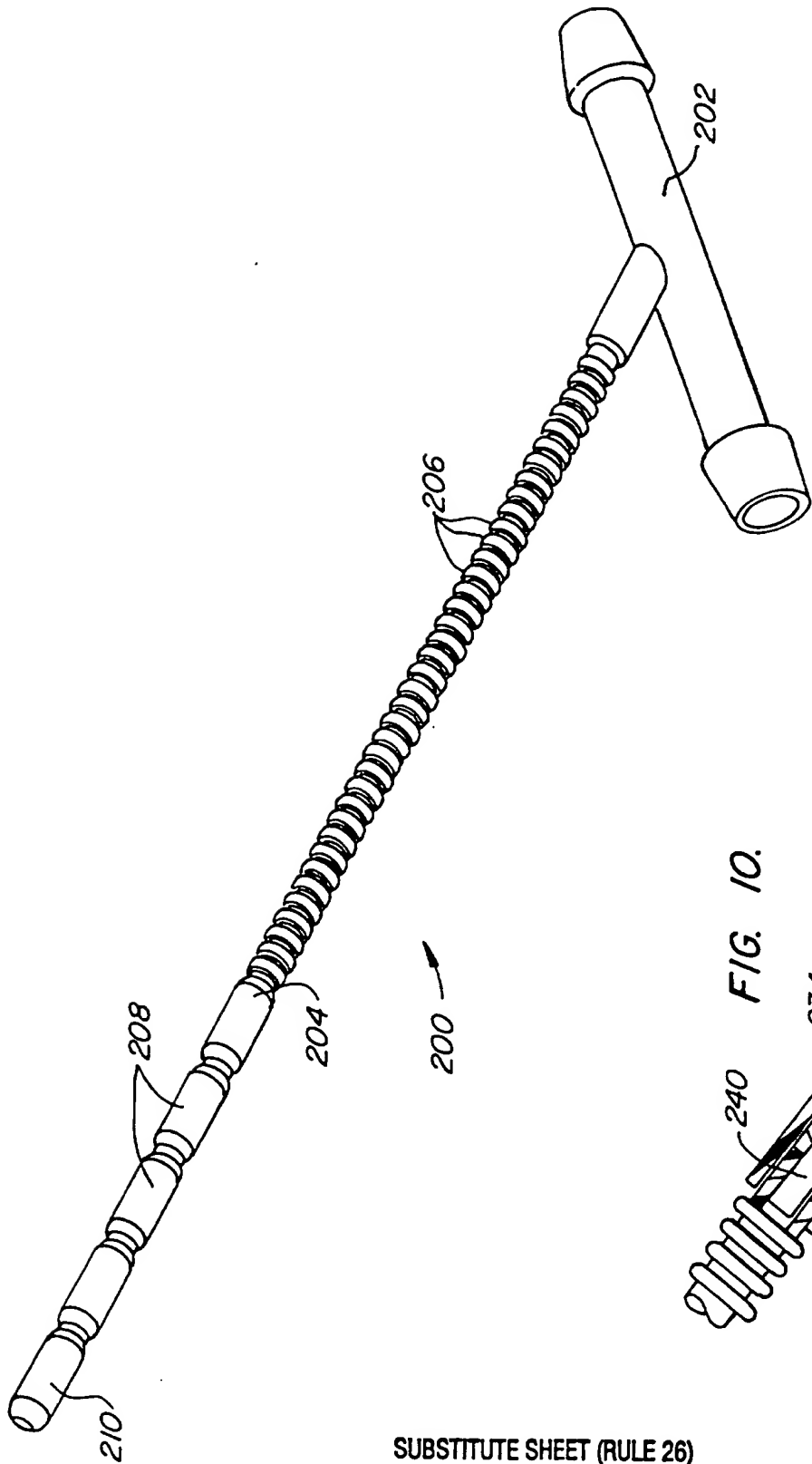


FIG. 9.

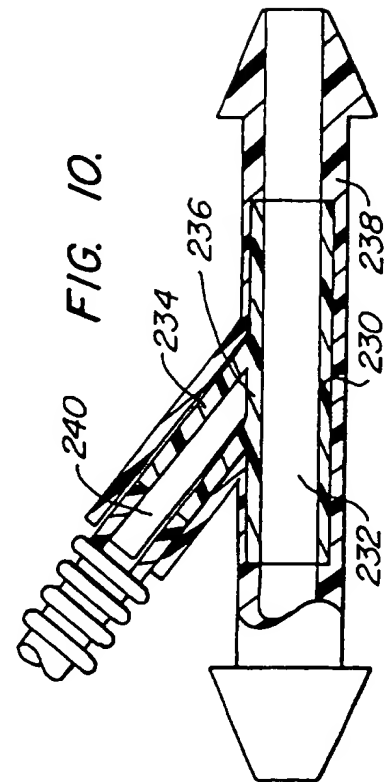


FIG. 10.

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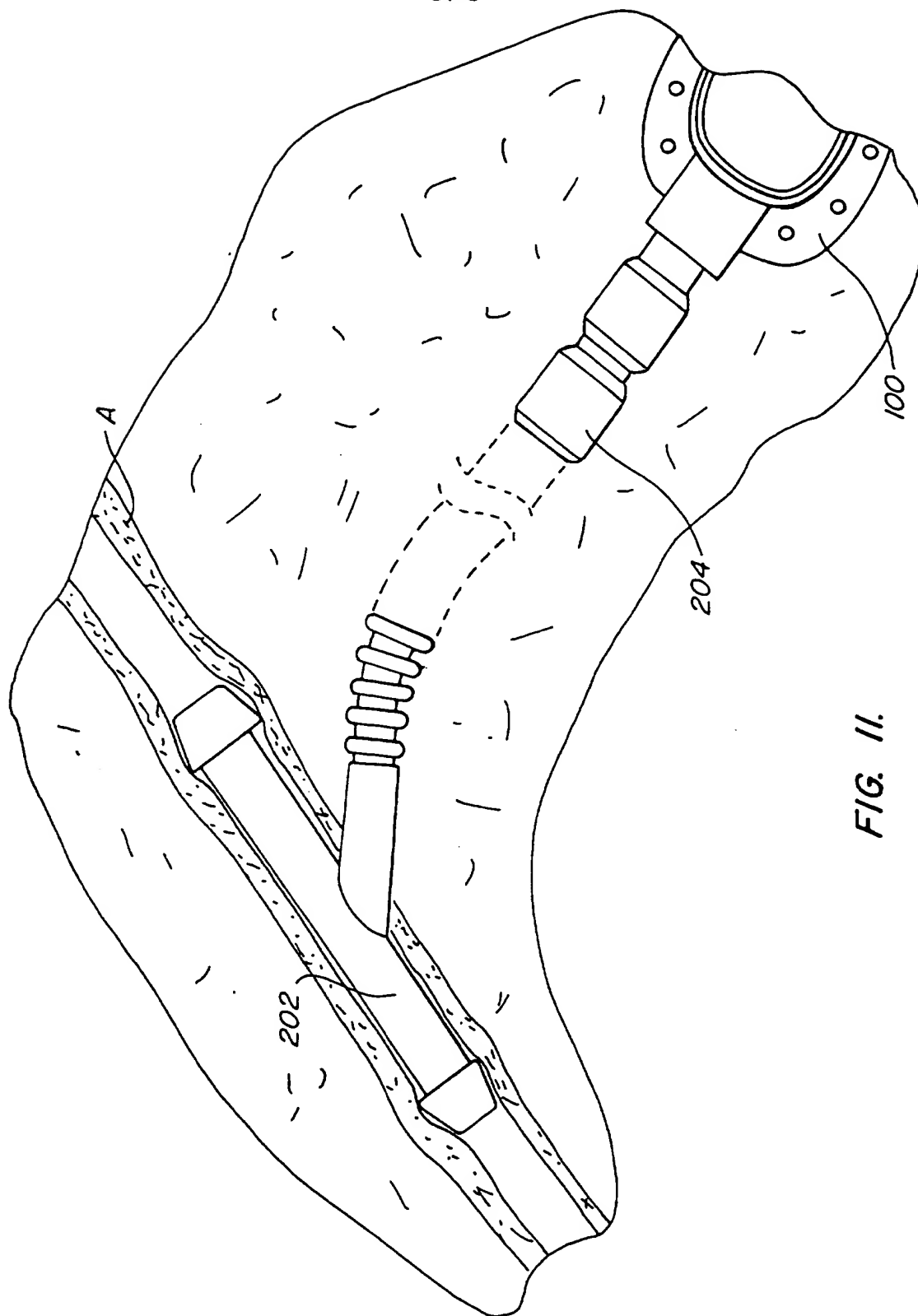


FIG. 11.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/15896

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00

US CL :604/49, 282, 284

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/4, 49, 264, 280, 282-284

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,822,341 A (COLONE) 18 April 1989, col. 6, 9-56.	1-4, 7, 8, 17, 20, 21
Y	US 3,924,632 A (COOK) 09 December 1975, abstract.	10-13, 23-26
A	US 5,421,814 A (GEARY) 06 June 1995, abstract.	1-56
A	US 5,344,568 A (KITAEVITCH et al) 06 September 1994, abstract.	1-56
A	JP 61-52710 A (FUJI SYSTEM KK) November 1986, abstract.	1-56

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 FEBRUARY 1997

Date of mailing of the international search report

28 FEB 1997

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